

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **March 30, 2023**

PROSOMNUS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-41567 (Commission File Number)	88-2978216 (IRS Employer Identification No.)
5675 Gibraltar Avenue Pleasanton, CA (Address of Principal Executive Offices)		94588 (Zip Code)

Registrant's telephone number, including area code: **(844) 537-5337**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	OSA	The Nasdaq Stock Market LLC
Warrants, each whole warrant exercisable for one share of Common Stock for \$11.50 per share	OSAAW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On March 30, 2023, ProSomnus, Inc. (the “Company”) issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference, announcing the release its financial results for the fourth quarter and year ended December 31, 2022 on Thursday, March 30, 2023, after the close of the financial markets.

The information disclosed under this Item 2.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, and shall not be deemed incorporated by reference into any filing made under the Securities Act, except as expressly set forth by specific reference in such filing.

Item 7.01. Regulation FD Disclosure.

Available Information

The Company maintains a website at the following address: www.ProSomnus.com. The information on the Company’s website is not incorporated by reference in this report. We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the Securities and Exchange Commission (“SEC”) in accordance with the Securities Exchange Act of 1934, as amended (“Exchange Act”). These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. We make this information available on our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. In addition, we routinely post on the “Investors” page of our website news releases, announcements and other statements about our business and results of operations, some of which may contain information that may be deemed material to investors. Therefore, we encourage investors to monitor the “Investors” page of our website and review the information we post on that page.

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at the following address: <http://www.sec.gov>.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 30, 2023
104	Cover Page Interactive Data (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROSOMNUS, INC.

By: /s/ Brian Dow

Name: Brian B. Dow

Title: Chief Financial Officer

Dated: March 30, 2023

ProSomnus Reports Fourth Quarter and Fiscal Year 2022 Financial Results

PLEASANTON, Calif., March 30, 2023 (GLOBE NEWSWIRE) -- ProSomnus, Inc. ("the Company") (NASDAQ: OSA), a pioneer in precision medical devices for the treatment of Obstructive Sleep Apnea (OSA), today announced financial results for the fourth quarter and fiscal year ended December 31, 2022.

Recent Business Highlights

- Generated revenues of \$5.8 million for the fourth quarter and \$19.4 million for the fiscal year 2022, an increase of 32% from the same period in 2021, and 38% year-over-year from 2021
- Surpassed 200,000 devices prescribed by healthcare providers
- Commenced execution of multiple growth initiatives, including the expansion of direct sales team in the U.S. and Europe, the commercialization of our next generation sensor device, the relocation to a new manufacturing facility, and the development of marketing and medical affairs programs
- Announced first patient enrolled in the Severe Obstructive Sleep Apnea (SOS) study
- Announced full enrollment of patients with moderate to severe obstructive sleep apnea in the First Line Obstructive Sleep Apnea Treatment (FLOSAT) study
- Began trading on the Nasdaq Stock Exchange in December under the ticker "OSA"

"2022 was a monumental year for ProSomnus," said Len Liptak, Chief Executive Officer. "ProSomnus generated record revenues and top decile growth rates, while getting the company publicly listed on the Nasdaq Stock Exchange in a challenging macroeconomic environment. We believe our rapid growth reflects increasing acceptance of our precision intraoral medical devices as a front-line treatment for mild and moderate OSA, and as a safe, effective, non-invasive, and easy-to-use alternative for patients who cannot tolerate CPAP. Listing ProSomnus on Nasdaq enables ProSomnus to access the capital markets necessary to accelerate our growth initiatives and establish ProSomnus devices as the leading option for the treatment and management of OSA."

Financial Results for the Fourth Quarter and Fiscal Year Ended December 31, 2022

Revenue for the three-month period and year ended December 31, 2022 totaled \$5.8 million and \$19.4 million, respectively, reflecting increases of 32% and 38% compared to \$4.4 million and \$14.1 million for the same periods during 2021. On a sequential quarter basis, revenue increased 16% compared to \$5.0 million for the three-month period ended September 30, 2022. Growth in revenue reflects increased volume in our EVO line of precision intraoral devices, with customer shipments of our EVO Select and EVO PH devices commencing during the fourth quarter of 2022. ProSomnus's EVO family of devices now accounts for 75% of revenue compared to 56% in the prior year and is accountable for substantially all of the growth reflected.

Gross Margin for the three-month period and year ended December 31, 2022 was 53.6% and 52.9% respectively reflecting modest improvements on a period over period basis from 51.4% and 51.9% for the same periods during 2021. On a sequential quarter basis gross margin improved from 49.2% for the three-month period ended September 30, 2022.

Sales and Marketing expense for the three-month period and year ended December 31, 2022 totaled \$2.4 million and \$8.9 million, respectively, reflecting increases of 44.8% and 53.5% compared to \$1.7 million and \$5.8 million for the same periods during 2021. On a sequential quarter basis, sales and marketing expense increased 4.1% compared to \$2.3 million for the three-month period ended September 30, 2022. Increases in the period presented reflect increases in headcount, principally direct sales personnel, increases in commissions paid commensurate with higher sales levels, and increased marketing activity.

Research and development expense for the three-month period and year ended December 31, 2022 totaled \$1.1 million and \$3.0 million, respectively, reflecting increases of 131.8% and 57.8% compared to \$0.5 million and \$1.9 million for the same periods during 2021. On a sequential quarter basis, research and development expense increased 54.8% compared to \$0.7 million for the three-month period ended September 30, 2022. Research and development expenses reflect the development expenses relating to the EVO Select and EVO PH products introduced during the fourth quarter, enrollment in the FLOSAT clinical study and ongoing development efforts into our next-generation sensor device with remote patient monitoring.

General and administrative expense for the three-month period and year ended December 31, 2022 totaled \$5.7 million and \$9.9 million, respectively. Current period general and administrative expenses reflect the costs incurred during the fourth quarter relating to the business combination of \$4.2 million including \$2.2 million of non-cash stock-based compensation.

Other income (expense) for the three-month period and year ended December 31, 2022 totaled \$8.3 million and \$4.3 million, respectively. Other income (expense) is comprised of interest expense on debt outstanding during the course of the period presented plus the periodic non-cash mark-to-market adjustments for instruments issued during the business combination. These mark-to-market adjustments impact the valuation adjustments tied to changes in our stock price between the business combination date and December 31, 2022.

Conference Call and Webcast Information

Interested parties may register for the conference call using the following link: [ProSomnus Q4 Earnings Registration Link](#). Participants may alternatively access the live webcast of the conference call by using the following link: [ProSomnus Q4 Earnings Call](#). The link will also be posted in the Investor Relations section of the ProSomnus website at News & Events.

About ProSomnus

ProSomnus (NASDAQ: OSA) precision intraoral medical devices offer effective, economical, and patient-preferred treatment for patients suffering from Obstructive Sleep Apnea (OSA). ProSomnus is the first manufacturer of mass-customized Precision Oral Appliance Therapy (OAT) devices to treat OSA, which affects over 74 million people in North America and is associated with serious comorbidities, including heart failure, stroke, hypertension, morbid obesity, and type 2 diabetes. ProSomnus's patented, FDA-cleared devices are a less invasive and more comfortable alternative to Continuous Positive Airway Pressure (CPAP) therapy, and lead to effective and patient-preferred outcomes. A growing body of research, including studies published by the *Journal of Clinical Sleep Medicine* and *Military Medicine*, suggests ProSomnus's Precision OAT devices are an effective treatment for mild to moderate OSA. Additional clinical research has

shown that ProSomnus's Precision OAT devices mitigate many of the side effects associated with alternative treatments and improve economics for payers and providers. With more than 200,000 devices delivered, ProSomnus's devices are the most prescribed Precision OAT in the U.S. ProSomnus's FDA-cleared devices are authorized by the Department of Defense and the U.S. Army, and are often covered by medical insurance, Medicare, and social health programs in key international markets. To learn more, visit www.ProSomnus.com.

Important Notice Regarding Forward-Looking Statements

This Press Release contains certain "forward-looking statements" within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, both as amended. Statements that are not historical facts, including statements about the parties' perspectives and expectations, are forward-looking statements. The words "expect," "believe," "estimate," "intend," "plan" and similar expressions indicate forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to various risks and uncertainties, assumptions (including assumptions about general economic, market, industry and operational factors), known or unknown, which could cause the actual results to vary materially from those indicated or anticipated.

Such risks and uncertainties include, but are not limited to: (i) the effect of the announcement or the business combination on ProSomnus's business relationships, operating results and business generally; (ii) risks that the business combination disrupts current plans and operations of ProSomnus; (iii) the outcome of any legal proceedings that may be instituted against ProSomnus or Purchaser related to the business combination; (iv) changes in the competitive industries in which ProSomnus operates, variations in operating performance across competitors, changes in laws and regulations affecting ProSomnus's business and changes in the combined capital structure; (v) the ability to implement business plans, forecasts and other expectations after the completion of the business combination, and identify and realize additional opportunities; (vi) the risk of downturns in the market and ProSomnus's industry including, but not limited to, as a result of the COVID-19 pandemic; (vii) costs related to the transaction and the failure to realize anticipated benefits of the transaction or to realize estimated pro forma results and underlying assumptions, including with respect to estimated stockholder redemptions; (viii) the risk of potential future significant dilution to stockholders resulting from lender conversions under the convertible debt financing; and (ix) risks and uncertainties related to ProSomnus's business, including, but not limited to, risks relating to the uncertainty of the projected financial information with respect to ProSomnus; risks related to ProSomnus's limited operating history, the roll-out of ProSomnus's business and the timing of expected business milestones; ProSomnus's ability to implement its business plan and scale its business, which includes the recruitment of healthcare professionals to prescribe and dentists to deliver ProSomnus oral devices; the understanding and adoption by dentists and other healthcare professionals of ProSomnus oral devices for mild-to-moderate OSA; expectations concerning the effectiveness of OSA treatment using ProSomnus oral devices and the potential for patient relapse after completion of treatment; the potential financial benefits to dentists and other healthcare professionals from treating patients with ProSomnus oral devices and using ProSomnus's monitoring tools; ProSomnus's potential profit margin from sales of ProSomnus oral devices; ProSomnus's ability to properly train dentists in the use of the ProSomnus oral devices and other services it offers in their dental practices; ProSomnus's ability to formulate, implement and modify as necessary effective sales, marketing, and strategic initiatives to drive revenue growth; ProSomnus's ability to expand internationally; the viability of ProSomnus's intellectual property and intellectual property created in the future; acceptance by the marketplace of the products and services that ProSomnus markets; government regulations and ProSomnus's ability to obtain applicable regulatory approvals and comply

with government regulations, including under healthcare laws and the rules and regulations of the U.S. Food and Drug Administration; and the extent of patient reimbursement by medical insurance in the United States and internationally. A further list and description of risks and uncertainties can be found in Lakeshore's initial public offering prospectus dated June 10, 2021 and in the Company's quarterly reports on Form 10-Q and annual reports on Form 10-K filed with the Securities and Exchange Commission (the "SEC") subsequent thereto and in the Registration Statement on Form S-4 and proxy statement that has been filed with the SEC by Lakeshore in connection with the business combination, and other documents that the parties may file or furnish with the SEC, which you are encouraged to read. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated or anticipated by such forward-looking statements. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements relate only to the date they were made, and the Company and its subsidiaries undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made except as required by law or applicable regulation.

PROSOMNUS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,916,141	\$ 1,500,582
Accounts receivable, net	2,843,148	2,098,982
Inventory	639,945	378,769
Prepaid expenses and other current assets	1,846,870	148,207
Total current assets	21,246,104	4,126,540
Property and equipment, net	2,404,402	3,356,595
Right-of-use assets, net	9,283,222	—
Other assets	262,913	154,797
Total assets	\$ 33,196,641	\$ 7,637,932
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 2,101,572	\$ 955,648
Accrued expenses	3,706,094	3,078,578
Revolving line of credit	—	587,816
Subordinated loan and security agreement	—	968,493
Equipment financing obligation	58,973	55,333
Finance lease liabilities	1,008,587	926,104
Operating lease liabilities	215,043	—
Total current liabilities	7,090,269	6,571,972
Subordinated loan and security agreement, net of current portion	—	6,589,563
Equipment financing obligation, net of current portion	185,645	244,617
Finance lease liabilities, net of current portion	2,081,410	866,853
Operating lease liabilities, net of current portion	5,525,562	—
Subordinated notes	—	7,331,254
Senior Convertible notes	13,651,000	—
Subordinated Convertible note	10,355,681	—
Earnout Liability	12,810,000	—
Warrant liability	1,991,503	562,244
Deferred rent	—	57,741
Total noncurrent liabilities	46,600,801	15,652,272
Total liabilities	53,691,070	22,224,244
Series B redeemable convertible preferred stock	—	12,389,547
Series A redeemable convertible preferred stock	—	26,245,000
Stockholders' deficit:		
Common stock	1,604	2,456
Additional paid-in capital	190,298,562	150,425,960
Accumulated deficit	(210,794,595)	(203,649,275)
Total stockholders' deficit	(20,494,429)	(53,220,859)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	\$ 33,196,641	\$ 7,637,932

PROSOMNUS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
For the years ended December 31, 2022 and 2021

	<u>2022</u>	<u>2021</u>
Revenue	\$ 19,393,343	\$ 14,074,649
Cost of revenue	<u>9,127,338</u>	<u>6,764,319</u>
Gross profit	10,266,005	7,310,330
Operating expenses		
Sales and marketing	8,865,328	5,776,084
Research and development	2,981,271	1,889,208
General and administrative	<u>9,894,899</u>	<u>4,467,576</u>
Total operating expenses	<u>21,741,498</u>	<u>12,132,868</u>
Loss from operations	<u>(11,475,493)</u>	<u>(4,822,538)</u>
Other income (expense)		
Interest expense	(6,119,806)	(3,245,220)
Loss on extinguishment of debt	(2,597,842)	—
Change in fair value of earnout liability	9,260,000	—
Change in fair value of warrant liability	3,234,586	(190,911)
Change in fair value of debt	553,235	—
Forgiveness of PPP loans	—	2,281,262
Total other income (expense)	<u>4,330,173</u>	<u>(1,154,869)</u>
Net loss	<u>\$ (7,145,320)</u>	<u>\$ (5,977,407)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.71)</u>	<u>\$ (1.51)</u>
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>10,021,632</u>	<u>3,957,783</u>

PROSOMNUS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three-month period ended		
	December 31, 2022	September 30, 2022	December 31, 2021
Revenue	\$ 5,792,312	\$ 4,997,979	\$ 4,402,974
Cost of revenue	2,686,863	2,540,287	2,138,216
Gross profit	3,105,449	2,457,692	2,264,758
Operating expenses			
Sales and marketing	2,415,155	2,319,362	1,667,995
Research and development	1,065,750	688,541	459,723
General and administrative	5,674,961	1,577,048	1,233,158
Total operating expenses	9,155,866	4,584,951	3,360,876
Loss from operations	(6,050,417)	(2,127,259)	(1,096,118)
Other income (expense)			
Interest expense	(2,405,029)	(1,421,702)	(939,802)
Loss on extinguishment of debt	(2,405,111)	—	—
Change in fair value of earnout liability	9,260,000	—	—
Change in fair value of warrant liability	3,255,342	—	(146,577)
Change in fair value of debt	553,235	—	—
Forgiveness of PPP loans	—	—	—
Total other income (expense)	8,258,437	(1,421,702)	(1,086,379)
Net loss	\$ 2,208,020	\$ (3,548,961)	\$ (2,182,497)

Investor Contact

Mike Cavanaugh

ICR Westwicke

Phone: +1.617.877.9641

Email: Mike.Cavanaugh@westwicke.com

Media Contact

Sean Leous

ICR Westwicke

Phone: +1.646.866.4012

Email: Sean.Leous@westwicke.com
